



## ENZYMATIC THERAPY INCORPORATED

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### INTEGRATIVE THERAPEUTICS INC.™

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9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 • F: 503.582.0467

### ENZYMATIC THERAPY™

&  
**PHYTOPHARMICA™**

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 • F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 • F: 920.469.4418 (Phyto)

August 13, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

AUG 21 2004

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
ITI Woman™	Supports healthy sexual drive, function and pleasure*	MacaPure (Lepidium meyenii), Ashwagandha (Withania somnifera) standardized to 4-5% withanolides, Rhodiola Rosea Extract 3% rosavins, Catuaba (Erythroxylum catuaba) 4:1 extract, Eleutherococcus senticosus extract standardized to .7-1% eleutherosides

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert C. Doster

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 8/13/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Michael P. Devereux  
Chief Financial Officer

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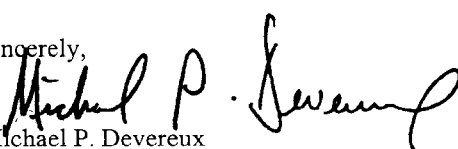
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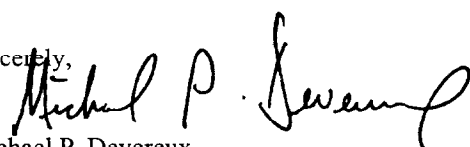
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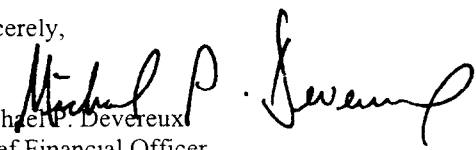
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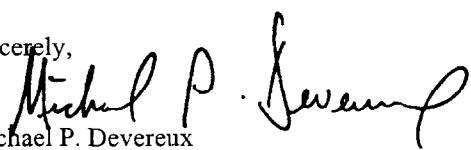
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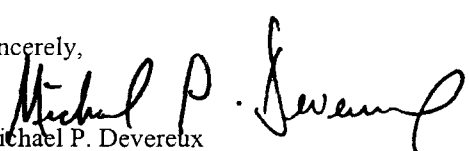
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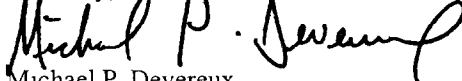
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ITI Woman™	Reclaim your sexuality and libido with ITI Woman.*	MacaPure (Lepidium meyenii), Ashwagandha (Withania somnifera) standardized to 4-5% withanolides, Rhodiola Rosea Extract 3% rosavins, Catuaba (Erythroxylum catuaba) 4:1 extract, Eleutherococcus senticosus extract standardized to .7-1% eleutherosides

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

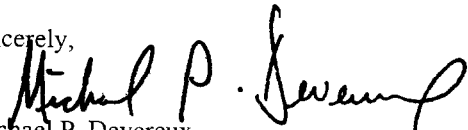
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

  
Michael P. Devereux  
Chief Financial Officer



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P: 920.469.9099 + F: 920.469.4418 (Phyto)

August 14, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
ITI Woman™	The ingredients in ITI Woman were specifically selected to help women cope with stress, increase energy, and improve sexual satisfaction.*	MacaPure (Lepidium meyenii), Ashwagandha (Withania somnifera) standardized to 4-5% withanolides, Rhodiola Rosea Extract 3% rosavins, Catuaba (Erythroxylum catuaba) 4:1 extract, Eleutherococcus senticosus extract standardized to .7-1% eleutherosides

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By: 


Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 8/14/04

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PRODUCT NAME	STATEMENTS	INGREDIENTS TO WHICH THE CLAIM REFERS
ITI Woman™	Uses of combination of herbal extracts long associated with energy, libido and performance in traditional cultures.*	MacaPure (Lepidium meyenii), Ashwagandha (Withania somnifera) standardized to 4-5% withanolides, Rhodiola Rosea Extract 3% rosavins, Catuaba (Erythroxylum catuaba) 4:1 extract, Eleutherococcus senticosus extract standardized to .7-1% eleutherosides

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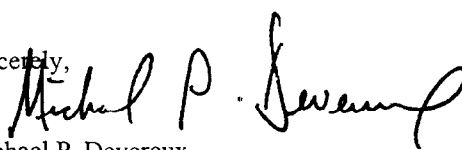
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
ITI Woman™	Alkaloids isolated from the maca root act upon the hypothalamus-pituitary axis, supporting and boosting energy levels and encouraging the production of sex hormones.*	MacaPure (Lepidium meyenii),

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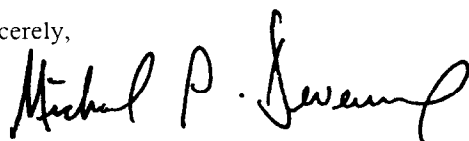
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August 16, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
ITI Woman™	Studies show ashwagandha supports red blood cell formation (which is very important for overall energy levels) and stress resistance.*	Ashwagandha (Withania somnifera) standardized to 4-5% withanolides

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By: \_\_\_\_\_

Robert C. Doster

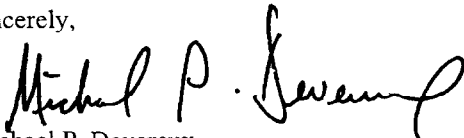
Title: Senior Vice President of Scientific Affairs

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8/16/04

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ITI Woman™	In one study, physical endurance was doubled in participants given extracts of withania somnifera.* The withanolides, compounds found in ashwagandha, appear to support the body's natural anti-stress abilities.*	Ashwagandha (Withania somnifera) standardized to 4-5% withanolides

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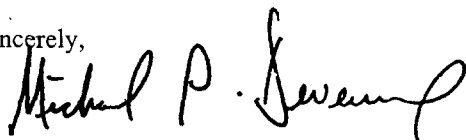
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 8/16/04

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
ITI Woman™	Rhodiola has been traditionally used in Scandinavia and Russia for centuries, to increase physical endurance, work productivity, longevity resistance to high altitude sickness, and a variety of other uses.*	Rhodiola Rosea Extract 3% rosavins

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

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Chief Financial Officer



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August 16, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
ITI Woman™	Rhodiola seems to act an adaptogen, helping the endocrine system adapt to environmental stresses.*	Rhodiola Rosea Extract 3% rosavins

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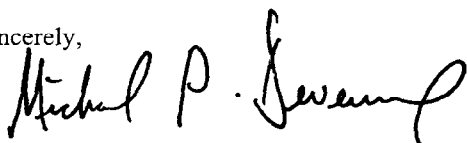
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<b>PRODUCT NAME</b>	<b>STATEMENTS</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
ITI Woman™	High stress is not associated with optimal sexual health, and in a clinical trial, rhodiola improved energy levels in 64% of participants.* Another clinical study showed rhodiola supports healthy reproductive cycles in over 60 percent of participants.*	Rhodiola Rosea Extract 3% rosavins

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By: \_\_\_\_\_

Robert C. Doster


Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

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<b>PRODUCT NAME</b>	<b>STATEMENTS</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
ITI Woman™	Extract of eleuthero bark has long been used in Asia for boosting energy levels and supporting endurance.*	Eleutherococcus senticosus extract standardized to .7-1% eleutherosides

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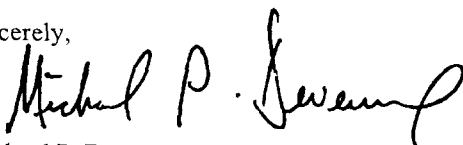
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
ITI Woman™	Eleuthero appears to help the body adapt to stress by supporting healthy adrenal gland function.*	Eleutherococcus senticosus extract standardized to .7-1% eleutherosides

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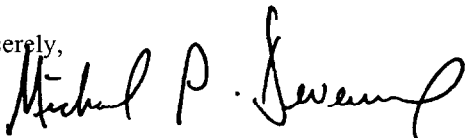
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RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
ITI Woman™	Catuaba (Erythroxylum catuaba) is a common tree found in South America from Brazil to Peru, in the same genus as the coco plant. Its bark has been consumed for centuries by natives and immigrants alike to support sexual function in men and women.*	Catuaba (Erythroxylum catuaba) 4:1 extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert C. Doster

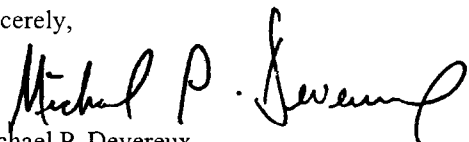
Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

8/17/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

  
Michael P. Devereux  
Chief Financial Officer



**ENZYMATIC THERAPY**  
INCORPORATED

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P: 920.469.9099 • F: 920.469.4418 (Phyto)

August 17, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
ITI Woman™	Supports healthy adrenal gland function, which boosts the body's energy levels during times of stress.*	MacaPure (Lepidium meyenii), Ashwagandha (Withania somnifera) standardized to 4-5% withanolides, Rhodiola Rosea Extract 3% rosavins, Catuaba (Erythroxylum catuaba) 4:1 extract, Eleutherococcus senticosus extract standardized to .7-1% eleutherosides

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

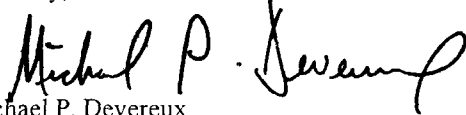
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date 8/17/04

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Michael P. Devereux  
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